

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

KATHLEEN PARADOWSKI, individually
and on behalf of a class of similarly situated
individuals,

Plaintiff,

v.

CHAMPION PETFOODS USA, INC. and
CHAMPION PETFOODS LP,

Defendants.

)
) Case No. 6:18-cv-01228-LEK-ML
)
)
) **PLAINTIFF'S MEMORANDUM IN**
) **OPPOSITION TO DEFENDANTS'**
) **MOTION TO EXCLUDE PLAINTIFF'S**
) **EXPERT WITNESS DR. GARY**
) **PUSILLO**

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I. INTRODUCTION

Plaintiff's expert, Dr. Gary Pusillo, is a highly qualified professional whose proffered opinions and testimony meets the relevance and reliability requirements of Rule 702 of the Federal Rules of Evidence ("Rule 702") and *Daubert v. Merrell DOW Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993) ("*Daubert*"). Each of Dr. Pusillo's opinions are based on his extensive qualifications and provide relevant insight into the fact that: (1) the Dog Food contains Heavy Metals and risks containing BPA, which were then consumed by dogs eating the Dog Food (*see* Ex. 1 at 5, Test Report Opinions 8, 14; Ex. 1 at 13, Evaluation Report Opinions 7, 20); (2) that the sources of Heavy Metals (as defined herein) and bisphenol A ("BPA ") in the Dog Food vary and can be controlled by reasonable manufacturing practices, such as the testing and certifying of ingredients for Heavy Metals that Dr. Pusillo himself has overseen (*see* Ex. 1 at 5, Test Report Opinions 9-13); and (3) that some of CPF's ingredients do not match its claims of Biologically Appropriate and Fresh Regional Ingredients ("Packaging Claims") (*see* Ex. 1 at 13, Evaluation Report Opinions 8-10, 12-13).¹ All of these opinions are at the crux of the present matter and will assist the trier of fact in understanding that a reasonable consumer, such as Plaintiff, would consider the presence of non-nutritious contaminants, such as Heavy Metals and BPA, to be material to their purchasing decision of the Dog Food.

¹ Plaintiff's claims are limited exclusively to the Acana Regionals Meadowland and Acana Heritage Free-Run Poultry diets ("Dog Food"). *See* Dkt. 115 (Order Regarding Claims at Issue (Mar. 19, 2021)). Unless otherwise noted, references to Exhibit 1-9 are to the exhibits attached to the Declaration of David A. Coulson in Support of Defendants' Motion to Exclude Plaintiff's Expert Witness Dr. Gary Pusillo (Dkt. 132-3 to 132-11). References to "Test Report Opinion ___" and "Evaluation Report Opinion ___" correspond to the remaining opinions at issue as highlighted in Exhibit 1 (Dkt. 132-3). Opinion numbers coincide with the opinion number displayed in the original documents. "CPF" refers to Champion Petfoods USA, Inc. and Champion Petfoods LP.

In its attempt to exclude Dr. Pusillo's opinions, CPF misstates Dr. Pusillo's opinions as "seek[ing] to testify that the mere presence of any level of heavy metals in Champion's dog food *causes* serious health problems." Dkt. 132-1 at 2 (Defs.' Motion to Exclude Plaintiff's Expert Witness Dr. Gary Pusillo ("Motion")). However, as indicated above and herein, Dr. Pusillo's stated opinions (1) do not claim that the Dog Food is unsafe; (2) do not attempt to establish proximate causation of an injury or death of a dog that consumed the Dog Food; and (3) do not attempt to establish that Plaintiff's dogs were injured or killed by Heavy Metals in the Dog Food.²

Disregarding the actual language of his opinions, CPF subjectively conflates and baselessly assumes that Dr. Pusillo's opinions amount to "insinuations that Champion's dog food is unsafe" and that Dr. Pusillo's claims leave "the implication ... that Champion's food is unsafe for dogs." Motion at 4, 7. At best, CPF's arguments for excluding Dr. Pusillo's opinions go to the weight, rather than the admissibility, of Dr. Pusillo's opinions. *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 354 (5th Cir. 2007) (quoting *Fed. Deposit Ins. Corp. v. Suna Assocs., Inc.*, 80 F.3d 681, 687 (2d Cir. 1996)) ("*FDIC*"); *In re Zyprexa Liability Litigation*, 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007) (quoting *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995)) ("Assertions that the witness lacks particular educational or other experiential background, 'go to the weight, not the admissibility, of [the] testimony.'") (alteration in original).³

CPF's criticisms do not justify the exclusion of Dr. Pusillo's opinions at this time, and should instead be raised and addressed through the traditional and appropriate means, such as cross examination, presenting contrary evidence, and careful instruction on the burden of proof.

² "Heavy Metals" shall refer to arsenic, cadmium, lead, and mercury.

³ Here, as throughout, all emphasis is deemed added and citations and footnotes are deemed omitted unless otherwise noted.

Regardless, CPF's distorted and inaccurate interpretation of Dr. Pusillo's opinions should be rejected, and Dr. Pusillo's relevant opinions, which he reached based on his extensive qualifications and reliable scientific methodology, should not be excluded.

II. LEGAL STANDARD

Rule 702 and *Daubert* govern the admissibility of expert testimony. *Doe v. Colgate Univ.*, No. 5:15-CV-1069, 2017 WL 4990629 (N.D.N.Y. October 31, 2017) (Kahn, J.) (citing *Daubert*, 509 U.S. 579, and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999)), *aff'd*, 760 F. App'x 22 (2d Cir. 2019). Under Rule 702,

[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. When evaluating expert opinions under Rule 702 and *Daubert*, "[t]he decision to admit expert testimony is left to the broad discretion of the trial judge." *McCulloch*, 61 F.3d at 1042.

Rule 702 is understood to be "a liberal standard of admissibility for expert opinions." *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 411 (S.D.N.Y. 2016). When evaluating a motion to exclude expert testimony under Rule 702 and *Daubert*, the district court considers whether the proffered expert (1) is qualified; (2) has employed a reliable methodology; (3) offers opinions that follow rationally from the application of the expert's methodology and qualifications; and (4) presents testimony that is relevant to the case at hand. *See Kumho Tire*, 526 U.S. at 151-54; *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *Daubert*, 509 U.S. at 589-93; *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir. 2017).

The first step in the *Daubert* inquiry under Rule 702 is to determine whether an expert is qualified to make his opinions. *Colgate Univ.*, 2017 WL 4990629, at *6; *Mirena*, 169 F. Supp. 3d at 412. "Courts within the Second Circuit have 'liberally construed expert qualification requirements.'" *Mirena*, 169 F. Supp. 3d at 412 (quoting *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, No. 00-CV-1898, 2008 WL 1971538, at *5 (S.D.N.Y. May 7, 2008)). "In keeping with the 'liberal thrust' of the Federal Rules and their 'general approach of relaxing the traditional barriers to 'opinion' testimony,' the standard for qualifying expert witnesses is liberal," *In re Zyprexa*, 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007) (quoting *Daubert*, 509 U.S. at 588-89), and "[a]ssertions that the witness lacks particular educational or other experiential background, 'go to the weight, not the admissibility, of [the] testimony.'" *Id.* (quoting *McCulloch*, 61 F.3d at 1044). "Since 'Rule 702 embodies a liberal standard of admissibility for expert opinions,' the assumption the court starts with is that a well-qualified expert's testimony is admissible." *Id.* (quoting *Nimely v. City of New York*, 414 F.3d 381, 395-96 (2d Cir. 2005)).

Next, the trial court must confirm that the expert's proffered opinions and testimony is relevant and will assist or "help the trier of fact." *Colgate Univ.*, 2017 WL 4990629, at *6; *see also Mirena*, 169 F. Supp. 3d at 412. The issue of relevance and helpfulness is described as a "consideration as one of 'fit,' requiring a 'valid scientific connection' between the subject matter of the expert's testimony and the factual issues to be determined by the jury." *Zyprexa*, 489 F. Supp. 2d at 283 (quoting *Daubert*, 509 U.S. at 591-92).

"Finally, the district court must determine whether the expert testimony is reliable." *Colgate Univ.*, 2017 WL 4990629, at *7 (citing *Daubert*, 509 U.S. at 593-94). Rule 702 and *Daubert* requires that an expert utilizes reliable, scientific methods to reach a conclusion, and does not require an expert's opinions to be "backed by published (and presumably peer-reviewed)

studies" but rather holds that a "lack of textual support may 'go to the weight, not admissibility'" of an expert's opinions. *Knight*, 482 F.3d at 354 (quoting *FDIC*, 80 F.3d at 687). When assessing an expert's reasoning and the reliability of his methods, "[t]he judge should only exclude the evidence if the flaw is large enough that the expert lacks 'good grounds' for his or her conclusions." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir.2002) (quoting *In re Paoli R.R. Yard PCB Litig.* 35 F.3d 717, 746 (3d Cir. 1994)). Indeed, the Second Circuit has gone so far as to even affirm the admission of a medical expert's testimony even though the expert "could not point to a single piece of medical literature" that specifically supported the expert's opinions and instead relied upon his background as an experienced and certified medical doctor. *McCulloch*, 61 F.3d at 1043-44. Dr. Pusillo's opinions face no such deficiency, however, as a review of the scientific literature relied upon by *both* parties' experts demonstrate that his opinions are supported by the relevant scientific literature.

III. DR. PUSILLO'S OPINIONS ARE BASED ON HIS EXTENSIVE QUALIFICATIONS, ARE RELEVANT, AND ARE RELIABLE

As the proffering party, Plaintiff has the burden of establishing the admissibility of Dr. Pusillo's opinions. *Colgate Univ.*, 2017 WL 4990629, at *6 (quoting *Mirena*, 169 F. Supp. 3d at 411 (citing *Bourjaily v. United States*, 483 U.S. 171, 175- 76 (1987))). For the reasons stated herein, Plaintiff has satisfied this burden because Dr. Pusillo's Heavy Metal, Packaging Claims, and BPA opinions are (1) based on his extensive qualifications; (2) relevant to the present issues; and (3) reached by utilizing reliable, scientific methodology.

A. Dr. Pusillo's Opinions Are Based on His Extensive Qualifications and Professional Experiences

CPF argues that Dr. Pusillo lacks sufficient expertise or background to enable him to offer these fourteen expert opinions. Motion at 5. Specifically, CPF argues that Dr. Pusillo must be either a toxicologist, chemist, veterinarian, food-safety expert, or an expert in BPA to offer his

opinions that (1) the Dog Food contains Heavy Metals and risks containing BPA, which are non-nutritious and undesirable chemical contaminants, that were then consumed by dogs that ate the Dog Food (Ex. 1 at 5, Test Report Opinions 8, 14; Ex. 1 at 13, Evaluation Report Opinions 7, 20); (2) that the sources of Heavy Metals and BPA in the Dog Food vary, but can be controlled by reasonable manufacturing practices that Dr. Pusillo himself has overseen (Ex. 1 at 5, Test Report Opinions 9-13); and (3) that some of CPF's ingredients do not match its Packaging Claims (Ex. 1 at 13, Evaluation Report Opinions 8-10, 12-13). CPF's argument that Dr. Pusillo is unqualified is factually incorrect and unsupported by the liberal frameworks set forth for the admissibility of expert opinions through Rule 702 and *Daubert*.

In fact, Dr. Pusillo's thirty years of knowledge, skill, experience, training, and education make him qualified to offer these expert opinion. *See* Dkt. 132-6 at 6-11 (Ex. 4, April 5, 2019 Evaluation of Champion Petfoods USA Inc., and Champion Petfoods LP for Safety ("Evaluation Report")); Dkt. 132-7 at 13-18 (Ex. 5, Test Results of Champion Petfoods USA, Inc., and Champion Petfoods LP for Heavy Metals and Plasticizers ("Test Report")). Dr. Pusillo has a Ph.D. in Animal Nutrition (received in 1986), an M.S. in Animal Production (received in 1984), and a B.S. in Animal Husbandry (received in 1980). Evaluation Report at 6. Dr. Pusillo holds relevant board certifications in: Diplomat American College of Animal Nutrition, since 1995; Professional Animal Scientist, 1986; American Association of Laboratory Animal Science Technologist, since 1979; Certified Microscopist, 1989; and American Academy of Forensic Sciences, full member

February 2015. *Id.*⁴ Further, he engages in continuing education relevant to his field⁵ and has drafted numerous articles and publications relating to, among other things, animal health and nutrition.⁶ Evaluation Report at 8-10.

Dr. Pusillo also possesses critical, hands-on experience relevant to his expert opinions. For example, Dr. Pusillo testified that he has managed and consulted for feed companies, including other pet food manufacturers, that were working towards testing every ingredient for heavy metals:

Q: Is it your opinion that every lot of ingredients coming into the kitchen should be tested for heavy metals?

A: There should be a COA [Certificate of Analysis] attached to it that they're—it's responsible for both as a supplier and—and also the receiver that their—the food is actually tested for heavy metals.

Q: Okay. Can you identify any dry kibble dog food manufacturer in the United States or the world that requires their suppliers to test every lot of every ingredient coming into their plant?

A: I know that I've worked with Purina, and their new policy is they test everything for heavy metals.

Q: Okay. So it is your testimony that Purina tests every lot of every ingredient for heavy metals.

⁴ Similarly, Dr. Pusillo belongs to the following relevant professional societies and organizations: American Academy of Forensic Sciences Member (AAFS); American Registry of Professional Animal Scientists (ARPAS); American Society of Animal Science (ASAS); American Dairy Science Association (ADSA); American Association of Small Ruminant Practitioners (AASRP); and Equine Science Society (ESS). *Id.* at 8.

⁵ Notably, Dr. Pusillo's continuing education courses include attending seminars related to toxicology and where lead, arsenic, cadmium, or mercury were topics of discussion. *See* Dkt. 132-8 at 215:19-216:14 (Ex. 6, April 26, 2019 Deposition of Dr. Gary Pusillo) ("Pusillo Dep. Vol. 1").

⁶ When CPF's counsel asked whether any of Dr. Pusillo's publications address certain heavy metals, he confirmed "[w]hen we do the -- for example, if we look at some of the beef cattle work that I've done with the oils, all the -- the feed that is tested is tested also for heavy metals, and we get a complete nutrition -- nutritional profile so that we know if there's any kind of confounding information." Ex. 6 at 234:17-24.

* * *

A: I think that's what they were trying to do to implement. I don't know if it's all totally been implemented."

Pusillo Dep. Vol. 1 at 92:1-23.

Dr. Pusillo's relevant work experience over the years has involved oversight of quality control for companies, including ensuring all ingredients purchased met guidelines and levels in order to provide a consistent product. *Id.* at 114:6-20. More specifically, he was involved in "testing protocols, SOPs for testing, cleaning, and everything involved with food safety." *Id.* at 114:21-24. Dr. Pusillo has also worked for companies that have developed or sell animal feed or pet food where he has reviewed test results for heavy metals. *Id.* at 220:16-25, 222:15-20.

Dr. Pusillo's qualifications become even clearer when compared to other experts that have been excluded for a lack of qualifications. When arguing that Dr. Pusillo should be excluded for being unqualified, CPF relies upon *Zaremba*, *Nora Beverages*, and *Prohaska* to provide examples of experts that have been excluded for a lack of qualifications. Motion at 4-6 (citing *Zaremba v. Gen. Motors Corp.*, 360 F.3d 355, 360 (2d Cir. 2004), *Nora Beverages, Inc. v. Perrier Group of Am., Inc.*, 164 F.3d 736, 746 (2d Cir. 1998), and *Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422, 435, 437 (W.D.N.Y. 2001)). However, the unqualified experts in *Zaremba*, *Nora Beverages*, and *Prohaska* are readily distinguishable from Dr. Pusillo's relevant credentials and demonstrate that Dr. Pusillo is qualified in the present matter. For example, the Second Circuit was critical of the expert in *Zaremba* who proposed an alternative design for removal glass roof panels for an automobile because (1) the expert "had only a bachelor's degree in engineering"; (2) the expert's only practical experience was "designing parts for automobile air bags"; and (3) the remainder of his professional career has consistent "entirely of consulting for purposes of litigation, primarily as an accident reconstructionist." *Zaremba*, 360 F.3d at 359-60.

Likewise, in *Nora Beverages*, the Second Circuit affirmed that an expert, who had only previously worked as a marketer in the beverage industry, was not qualified to testify on contract negotiations because he admitted that he was "never directly involved in negotiating co-packing agreements" and "could not recall the details of any co-packing agreements into which his company entered." *Nora Beverages*, 164 F.3d at 746. Similarly, in *Prohaska*, the court excluded an expert from a case alleging a defective medical device because said expert (1) never implanted such a device; (2) could not distinguish between the at-issue defective device from alternative devices; (3) never reviewed medical literature concerning the safety or efficacy of the at-issue defective device; and (4) instead relied almost entirely on counsel provided information, which he "accepted as 'gospel.'" *Prohaska*, 138 F. Supp. 2d at 435-37. Simply put, Dr. Pusillo's educational (animal nutrition) and experiential (consultant and manager for pet food manufacturers) is readily distinguishable from the unqualified experts CPF offers in comparison. CPF essentially argues that Dr. Pusillo should be "exclude[d] ... solely on the ground that the witness lacks expertise in the specialized areas," which has been routinely held as unpersuasive and should be rejected. *See Zyprexa*, 489 F. Supp. 2d at 282 (E.D.N.Y. 2007) (citing *Stagl v. Delta Air Lines, Inc.*, 117 F.3d 76, 80 (2d Cir. 1997)).

Moreover, Dr. Pusillo has already been qualified in a related case. In the recent decision in *Zeiger v. WellPet, LLC*, the court confirms that Dr. Pusillo is "an experienced animal nutritionist" and is "qualified to opine about the effects of substances that animals ingest on their health." *Zeiger v. WellPet, LLC*, No 3:17-cv-04056-WHO, 2021 WL 756109, at *5 (N.D. Cal. Feb. 26, 2021). In *Zeiger*, Dr. Pusillo was qualified regarding the prevention of Heavy Metals, with the court noting that "[t]he removability of these substance[s]" in reference to Heavy Metals, "is currently a matter of expert debate" between Dr. Pusillo and WellPet's expert, Dr. Robert

Poppenga. *Id.* at *19. Plaintiff agrees with CPF's distinction of *Zeiger* to the extent that safety is not at issue in the present matter. Motion at 6 n.3. However, Plaintiff adds that even if CPF was correctly characterizing Dr. Pusillo's opinions in the present matter as relating to safety (which it is not), *Zeiger* evidences Dr. Pusillo is qualified to do so. *Zeiger*, 2021 WL 756109, at *5. Indeed, *Zeiger* demonstrates that Dr. Pusillo is more than readily qualified to provide his proffered opinions in the present matter, such as his opinion that the presence of Heavy Metals is undesirable given their lack of nutritional value, and that pet food manufacturers, such as CPF, have the ability to implement manufacturing practices to reduce or remove Heavy Metals and BPA entirely from its Dog Food, such as selective ingredient sourcing.

B. Dr. Pusillo's Heavy Metal Opinions Are Relevant

Dr. Pusillo's opinions regarding the presence of Heavy Metals in the Dog Food and the pet food manufacturing practices are relevant for the trier of fact when assessing (1) whether a reasonable consumer would have expected the Dog Food to not contain Heavy Metals; and (2) whether the presence of these undesirable, unnatural contaminants is material to the reasonable consumer when purchasing dog food.

Although Dr. Pusillo offers six opinions related to Heavy Metals, CPF predominately rests their argument that these six opinions should be excluded because Dr. Pusillo's opinion that the Dog Food is "not tested and certified for safety for dogs" is supposedly irrelevant. Motion at 7. CPF claims that Dr. Pusillo is unable to explain what "certified for safety for dogs" even means, and that this opinion should be excluded as irrelevant and unhelpful. *Id.* That is incorrect. Dr. Pusillo has explained in his reports and depositions that his relevant opinion that CPF failed to "test[] and certify[] for safety for dogs" regarding Heavy Metals is based on CPF's failure to (1) adequately test its ingredients for Heavy Metals; (2) remove ingredients with Heavy Metals to the extent possible; and (3) to ensure appropriate standard operating procedures ("SOP") are

implemented in CPF's manufacturing practices to reduce or even prevent the inclusion of Heavy Metals in the Dog Food. Evaluation Report at 17:539-41, 18:606-14, 18:616-21, 19:626-35; *see also* Pusillo Dep. Vol. 1 at 27:19-28:18, 138:23-139:2

Dr. Pusillo's reports and opinions are relevant because they shed light on the poor manufacturing practices that resulted in the Dog Food containing Heavy Metals. *See* Evaluation Report at 18:616-21 ("If heavy metals are so widespread and they cannot be avoided, ***it is Champion Petfoods' duty to minimize the exposure to pets by using the best ingredients possible. There must be an appropriate SOP in place to prevent the contamination of pet foods with heavy metals.***") For example, Dr. Pusillo's reports outline how CPF's minimal testing for heavy metals (at most once per year) is improper, as this limited testing fails to take into consideration the variation in Heavy Metals among different fish species, seasons, and regions. *Id.* at 17:539-41. Dr. Pusillo explains that manufacturers should evaluate the presence of Heavy Metals when considering whether to use specific ingredients in its Dog Food and should test ingredients for Heavy Metals before adding said ingredients to the Dog Food. *Id.* at 19:626-35. Dr. Pusillo's opinions that CPF does not have adequate quality control measures in place, such as a lack of Heavy Metal testing on ingredients and finished products, is relevant to whether CPF failed to meet consumer expectations as to the quality of its Dog Food with regards to Heavy Metals based on CPF Packaging Claims.

During his April 29, 2019 Deposition, Dr. Pusillo explains how CPF fails to "test and certify" the Dog Food for Heavy Metals because CPF did not sufficiently test its ingredients for Heavy Metals:

Q: Okay. What do you mean by "the levels of safety"?

A: As I was looking through a lot of the products and the ingredients that were used, there were ***some ingredients that were not tested at the level I would expect for a product that is claimed to be the world's best pet food.***

Q: And what do you mean by "levels of safety"?

* * *

A: I use it according to what was asked for in a lot of the testing documents that they're—the submission documents to Eurofins, what was asked for testing, and also some of the incoming ingredient control sheets that ***I would expect a company of this magnitude and size and sophistication to—to test for specific types of safety areas.***

Q: Well, again, what do you mean by "levels of safety" as you use it in the context of paragraph 7, summary of opinions?

A: Well, the level of safety will vary according ***to the type of ingredient used, is dependent on the ingredient and what testing is done on that ingredient and how that test result is used to make the formulation.***

Pusillo Dep. Vol. 1 at 27:19-28:18.

During his April 29, 2019 Deposition, Dr. Pusillo offered additional clarification as to the good manufacturing practices that CPF could have employed to reduce or prevent the presence of Heavy Metals. For example, Dr. Pusillo testified that CPF could remove or limit Heavy Metals from its Dog Food by purchasing ingredients without Heavy Metals. *Id.* at 138:23-139:2. CPF's own testing results show that fresh meat ingredients, such as deboned chicken, can be purchased without detectable amounts of heavy metals. *See* Dkt. 108-32 (CPF0217103, filed as Exhibit 31 to Plaintiff's Motion for Class Certification) (CPF third party testing showing non-detectable amounts of heavy metals in deboned chicken). Put differently, Dr. Pusillo's recommendation that CPF screens its ingredients for Heavy Metals is not only relevant, but feasible.

Dr. Pusillo's reports and opinions are further relevant as they explain how Heavy Metals are undesirable contaminants in the Dog Food. For example, Dr. Pusillo describes how Heavy Metals have "no biological role" in a dog's nutrition, and that none of the Heavy Metals are "accepted as an essential nutrient for higher animals." Evaluation Report at 18:606-14. However, CPF does not address these relevant opinions offered by Dr. Pusillo, and instead alters his opinions

to the "extreme and unsupported position that the mere presence of heavy metals in dog food—in *any amount*—can *cause* these maladies, which Plaintiff's dogs have not suffered." Motion at 11.

Plaintiff alleges that CPF's Packaging Claims are misleading because a reasonable consumer would not expect the Dog Food to contain Heavy Metals, as Heavy Metals are undesirable contaminants that offer no nutritional value. *See* Dkt. 76, ¶¶1-9 (Second Amended Complaint) ("SAC"). Dr. Pusillo's opinions regarding the presence of Heavy Metals, as well as CPF's ability to avoid Heavy Metals, is relevant to the trier of fact when assessing these allegations regarding Heavy Metals.

C. Dr. Pusillo's Heavy Metal Opinions Are Reliable

Dr. Pusillo's opinions are based on the uniformly recognized fact that Heavy Metals are non-nutritious and undesirable contaminants and thus, that pet food manufacturers (such as CPF) should improve its manufacturing practices to seek to minimize Heavy Metals, even when Heavy Metals might be present below the National Research Council's ("NRC") Maximum Tolerable Levels ("MTLs"). Such opinions are scientific and reliable because Heavy Metals are in fact recognized as non-nutritious and undesirable contaminants.

CPF, on the other hand, attempts to characterize Dr. Pusillo's opinions as unreliable and unscientific within the framework of a toxic tort case. Motion at 8-10. CPF points to the dose-response relationship and NRC MTLs, suggesting that both render Dr. Pusillo's opinions as unscientific and unreliable. *Id.* However, the dose-response relationship is entirely irrelevant and unhelpful to the present matter because Plaintiff is not attempting to establish that the Dog Food was the proximate cause of any harm to her dogs.

In support of its misplaced argument, CPF points to inapposite toxic tort cases, like *McClain*, without addressing the fact that dose-response relationships relied upon in these cases is only relevant because the *plaintiff is attempting to prove the proximate cause for an injury*

allegedly caused by a chemical or toxic exposure from a product. *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1242 (11th Cir. 2005). Indeed, CPF cites to *McClain* while glossing over that its excerpt specifically makes this distinction: "Dose is the single most important factor to consider in evaluating *whether an alleged exposure caused a specific adverse effect.*" Motion at 9 (quoting *McClain*, 401 F.3d at 1242 (product liability case for unreasonably dangerous diet drug that allegedly caused ischemic strokes and heart attacks)).

Again, Plaintiff is not attempting to prove a proximate cause for an injury to the dogs at-issue in this action. CPF assumes, in error, that Dr. Pusillo intends to "detail to the jury a laundry list of severe illnesses purportedly *caused* by naturally occurring heavy metals without providing any context or benchmark for what level of exposure, and length of exposure to heavy metals could potentially trigger these maladies." Motion at 11. But as noted above, Dr. Pusillo's Heavy Metal opinions are not about causation but about Heavy Metals, their lack of nutrition and the ability to minimize them from products such as dog food. Dr. Pusillo's opinions outline how (1) Heavy Metals vary by region and ingredient; (2) Heavy Metals are non-nutritious contaminants that are undesirable in the Dog Food; and (3) that CPF should improve its manufacturing practices to limit or prevent the presence of Heavy Metals. All of these opinions were reached by Dr. Pusillo based on his expertise in pet food manufacturing and animal nutrition and by reviewing CPF manufacturing practices and Heavy Metal testing.

CPF also wrongly argues that the NRC MTLs suggest that Dr. Pusillo's opinions are not based on a reliable, scientific methodology because CPF "ensure[s] that its products sold to the public remain significantly below those established levels." Motion at 11. CPF's criticisms of Dr. Pusillo are missing the point. The point is that no level of Heavy Metals is beneficial and that steps can be taken to reduce or minimize the non-nutritious contaminants. A review of scientific

literature, including studies relied upon by CPF's own expert, demonstrates that the scientific community often agrees with Dr. Pusillo and Plaintiff, by specifically discussing how the presence of Heavy Metals in dog food is undesirable, and that the presence of heavy metals, even below the NRC MTLs, should be communicated to consumers:

- "[A]lthough the products that we examined appear to be safe for consumption ... *consumers may want to solicit information from companies regarding heavy metal contamination before purchase.*"⁷
- "The trace-element data [of heavy metals] generated in this study have shown that there *might be a cause of concern for owners who feed their pets commercially available dog and cat food*"⁸
- "*This subject [of heavy metals] is increasingly present in the field of pet food, although the amount of available research is still limited.*"⁹
- "*[I]nformation provided on the dog food label should be helpful for the owner and include detailed information concerning not only the ingredients list, but also*

⁷ See generally Dkt. 144-9 at 6-7 (Kim et al., Evaluation of Arsenic, Cadmium, Lead and Mercury Contamination in Over-the-Counter Available Dry Dog Foods with Different Animal Ingredients (Red Meat, Poultry, and Fish), *Frontiers in Veterinary Science*, 5:264 (2018), filed as Exhibit 7 to the Declaration of Rebecca A. Peterson in Support of Plaintiff's Motion to Exclude Defendants' Expert Witness, Dr. Robert H. Poppenga ("Peterson Decl. to Poppenga Mot.")).

⁸ See Dkt. 144-10 at 11 (P. Atkins et al. (2011): Analysis of Toxic Trace Metals in Pet Foods Using Cryogenic Grinding and Quantitation by ICP-MS, Part 1, filed as Exhibit 8 to Peterson Decl. to Poppenga Mot.).

⁹ See Dkt. 144-12 at 2, 17 (Katarzyna Kazimierska et al., Mineral Composition of Cereal and Cereal-Free Dry Dog Foods versus Nutritional Guidelines, *Molecules*, Nov. 6, 2020, filed as Exhibit 10 to Peterson Decl. to Poppenga Mot.).

the nutritional value (incl. nutrient levels and mineral content) and feed additives used."¹⁰

- *"The information provided on the dog food label should be more comprehensive and include detailed information concerning mineral content."*¹¹

Dr. Pusillo's opinions regarding the undesirable presence of Heavy Metals in the Dog Food and the steps that CPF could (and should) have taken to reduce or prevent Heavy Metals is based on his review of CPF manufacturing practices and Heavy Metal test results, and, relying on his experiences and qualifications, identified quality assurance gaps in CPF manufacturing practices that allow the Dog Food to contain concerning amounts of Heavy Metals. Dr. Pusillo's opinions that the presence of Heavy Metals is undesirable, even at levels below the NRC MTLs, is sufficiently reliable as these very same opinions are accepted within the scientific community, including in the materials relied upon by both parties.

D. Dr. Pusillo's Opinions Regarding CPF Packaging Claims Are Helpful to the Jury

In addition to Dr. Pusillo's above-discussed opinions regarding Heavy Metals, Dr. Pusillo also has valid, relevant, helpful opinions regarding the misleading nature of the CPF packaging. More specifically, Dr. Pusillo's opinions that the Dog Food is "not in agreement" with CPF Packaging Claims are relevant and helpful to the jury. *See* Ex. 1 at 5, Evaluation Report Opinion 8. As an animal nutritionist, Dr. Pusillo is qualified to opine as to whether the Dog Food (as opposed to specific ingredients) are Biologically Appropriate and whether the Dog Food is made with Fresh Regional Ingredients. In an attempt to argue that Dr. Pusillo's packaging opinions

¹⁰ *Id.* at 2.

¹¹ *Id.* at 20.

should be excluded, CPF cherry picks excerpts from Dr. Pusillo's deposition and ignores that Dr. Pusillo continued to testify and explain that non-fresh ingredients, especially those that contain Heavy Metals (such as the processed meal ingredients used in the Dog Food) are not in agreement with CPF Packaging Claims. Motion 13-16.

Dr. Pusillo testified that the presence of Heavy Metals in the Dog Food and the ingredients that make up the Dog Food are not in agreement with CPF's Biologically Appropriate claim:

Q: Sir, if the lead, cadmium, arsenic or mercury are naturally occurring in these meats that are being used, how does that take away from the ingredients being biologically appropriate?

A: Because they're not ... needed for nutrition. Especially they have no nutritional basis for their function for most of the species, so ... it's a contaminant—we don't feed contaminated food to animals. We try not to.

Pusillo Dep. Vol. 1 at 262:4-12.

Dr. Pusillo next testified that the non-fresh, processed meal ingredients used in the Dog Food are not Biologically Appropriate for dogs. *Id.* at 261:12-20. CPF ignores that Dr. Pusillo specifically said that CPF's use of non-fresh ingredients was not in agreement with CPF's Biologically Appropriate claim:

Q: What ingredients in Champion Petfoods dog foods are not in agreement with Champion's definition of Biologically Appropriate?

A: Well, the idea of being fresh was one of them. A lot of the ingredients were meals. They weren't fresh meat

Id. at 45:10-16.

Indeed, CPF relies upon deposition excerpts from Dr. Pusillo wherein he specifically qualifies that non-fresh ingredients are inconsistent with the Biologically Appropriate claim:

Q: And so you have no such opinion sitting here today; is that correct?

A: Well, as I said, *the freshness issue is one that I brought up.*

Q: All right. *Well putting aside freshness. I'm just talking about ingredient itself*
....

Pusillo Dep. Vol. 1 at 45:25-46:5.¹²

Dr. Pusillo continues by noting that CPF's use of processed meal ingredients is also inconsistent with CPF's Packaging Claim of Fresh Regional Ingredients, because "obviously meals aren't fresh" and "a lot of the food they're using" in the Dog Food "is not fresh." *Id.* at 196:3-7. Dr. Pusillo also identified these processed, non-fresh meals as an ingredient that was not in agreement with CPF's Packaging Claim of Whole Prey. *Id.* at 54:3-7. Although not at issue, Dr. Pusillo's opinions as to Whole Prey underscore the misleading nature of CPF's Packaging Claims.

As an animal nutritionist, Dr. Pusillo is relying on his educational background, scientific expertise and professional experience to opine as to how an animal nutritionist would understand CPF's Packaging Claims. According to Dr. Pusillo, non-fresh ingredients, such as meal ingredients and ingredients that contain Heavy Metals, "are not in agreement" from a nutritional perspective with regards to CPF's Packaging Claims of Biologically Appropriate and Fresh Regional Ingredients. Unlike experts in *Berk* and *Amorgianos*, Dr. Pusillo's opinions regarding these Packaging Claims were the product of his stated, reliable methodology of reviewing CPF manufacturing processes and ingredients, and assessing these facts using his expertise in animal nutrition and pet food manufacturing. *Berk v. St. Vincent's Hosp. and Med. Ctr.*, 380 F. Supp. 2d 334, 355-56 (S.D.N.Y. 2005); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268-269 (2d Cir. 2002).

¹² While CPF relies upon this deposition excerpt, Plaintiff notes that CPF tellingly omitted (and declined to highlight in its exhibit) that CPF counsel "put aside fresh" ingredients when asking Dr. Pusillo about ingredients that "are not in agreement" with Biologically Appropriate. *Id.*

These opinions are relevant and assist the trier of fact in determining whether CPF's Packaging Claims are misleadingly advertised given the presence of Heavy Metals and non-fresh ingredients.

E. Dr. Pusillo's Opinions Regarding BPA Are Relevant and Based on Reliable, Scientific Methodology

Finally, like his Heavy Metal opinions, Dr. Pusillo's testimony and opinions regarding BPA are relevant, helpful, and reliable, because they shed light on the poor manufacturing practices that resulted in the Dog Food containing BPA. Again, Dr. Pusillo testified as to how good manufacturing practices can avoid the risk of the Dog Food containing BPA, such as Dr. Pusillo's own professional experiences wherein he required plastic suppliers to test and prove that BPA was not present in the finished pet food product that he sold:

Q: But have you seen any testing results for BPA or plasticizer testing for the Fresh Oasis Product?

A: Yes, because ... years ago when we put this together, that was part of the ... agreement of having them ... manufacture it.

Q: Alright ... are you going to go back and have your product tested, make sure there's zero levels of ... BPA in it?

A: They're ... going to continue to do their testing as they ... have been.

Pusillo Dep. Vol. 1 at 231:3-14.

CPF points to the non-detection of BPA in the samples of the Dog Food from Dr. Pusillo to argue that Dr. Pusillo's BPA opinions are "speculation" and "irrelevant." Motion at 18. However, Dr. Pusillo's opinions on the potential source of BPA contamination from plastic used when manufacturing and packaging the Dog Food is based on the totality of evidence, including Plaintiff's other testing and CPF's own testing that establishes that the Dog Food has the risk of containing BPA. *See* Evaluation Report at 34 (list of BPA detected in Acana Heritage Free Run Poultry at 62.2 parts per billion ("ppb"); and Acana Regionals Meadowland at 82.7 ppb). More

importantly, the non-detection of BPA in *some* of the Dog Food test results demonstrates that CPF can (and should) ensure that *all* of its Dog Food is manufactured without containing BPA. CPF's reliance on *Zaremba* is again distinguishable, as Dr. Pusillo is qualified to make these relevant opinions regarding BPA and how the use of plastics when manufacturing the Dog Food exposes the Dog Food to the risks of BPA. *See Zaremba*, 360 F.3d at 358.

IV. CONCLUSION

For the foregoing reasons, CPF's Motion should be denied in its entirety.

Dated: June 8, 2021

LOCKRIDGE GRINDAL NAUEN P.L.L.P.

By: /s/ Rebecca A. Peterson

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 8th day of June, 2021, I served the foregoing document on all counsel of record via the Court's electronic delivery system.

s/ Rebecca A. Peterson

Rebecca A. Peterson